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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,664	08/05/2003	Steven J. Rychnovsky	0130541	3817
7590	10/04/2005		EXAMINER	
Christopher J. Hayes BRYAN CAVE LLP Suite 3600 211 N. Broadway St. Louis, MO 63102-2750			FARAH, AHMED M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,664

Applicant(s)

RYCHNOVSKY ET AL.

Examiner

Ahmed M. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/17/04; 5/13/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10. When two claims in an application are duplicates or else are so close in

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content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 10, 11, 13, 15-23, 24-27, and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahota et al. U.S. Patent No. 5,417,653.

Sahota et al. disclose a light angioplasty catheter system 10 and method for introducing treatment light into a body lumen, the catheter system 10 comprising:

an elongate tubular shaft 15 having a proximal end and a distal end, the proximal end adapted to remain outside of the body lumen;

a light guide (optical fiber 26) in the catheter shaft for transmitting light from light source 30 to a treatment site (see Fig. 1);

at least one occlusion balloon positioned on the distal end of the catheter shaft adjacent to the treatment site (see Figs. 1 and 3);

an inflation lumen in the catheter shaft and in fluid communication with the balloon for delivering inflation fluid to the balloon; and

an infusion lumen and plurality of infusion ports formed on the distal end of the catheter adjacent the treatment site for delivering infusion fluid to the body lumen (see col. 3, line 64 through col. 4, line 14).

As to claims 10 and 11, see col. 4, lines 28-31.

As to claims 13, 15-17 and 23, see Fig. 4; col. 3, lines 33-44 and lines 54-57; col. 6, lines 33-40 and col. 7, lines 37-41.

As to claims 18 -20, see col. 4, lines 16-58.

As to claims 21 and 22, the recited limitations are intended use of the catheter device and therefore are not given a patentable weight.

Claims 28-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. U.S. Patent No. 5,104,392.

Kittrell et al. disclose a laser catheter for insertion into a blood vessel, the catheter device adapted for the diagnosis of a diseased tissue within the blood vessel, and to provide controlled delivery of a laser energy to treat said tissue. Their catheter system comprises:

an elongate tubular shaft 16 having a proximal end and a distal end, the proximal end adapted to remain outside of the patient's body (see Figs. 1 and 24);

a light guide (optical fibers 20) in the catheter shaft for transmitting light from a light source 92 to a treatment site;

a light detection optical fiber in the catheter shaft for detecting light transmitted by the light delivery optical fiber as claimed (see Fig. 21); and

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a fluorescent material incorporated into the distal end of the catheter shaft to provide a backscattered fluorescent emission, wherein the fluorescent emission is used for monitoring the treatment as presently claimed (see col. 9, lines 13-24).

As to claim 29, Kittrell et al. disclose that, in certain embodiments, the optical fibers are terminated with a diffuser tip at the distal end (see Figs. 7D, 13B, and 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota et al. (US Pat. '653).

Although Sahota et al, described above, teach that infusion ports can have any of variety of forms and different configurations, they do not specifically recite the shape, number and/or locations of the infusion ports.

However, the applicants have not disclosed that the shape, dimensions or configuration of the infusion ports provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to use different forms/shapes of infusion ports. It would have been further obvious to one skilled in the art to arrange the infusion port on the catheter body as suitable for the desired treatment. Furthermore,

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one skilled in the art would have expected Applicants' invention to perform equally well with infusion ports having various shapes because no advantage is disclosed.

Claims 7-9, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota et al. in view Kittrell, described above, and Sinofsky U.S. Patent No. 4,852,567.

Sahota et al., described above, do not teach a catheter device terminating a diffuser tip, or a second optical fiber for collecting a backscattered light from the treatment site. However, Sinofsky teaches an alternative medical catheter, comprising an optical fiber 16 having a distal end terminating in a diffuser tip. Kittrell et al., described above, also disclose a medical catheter comprising optical fibers terminating in diffuser tips, and at least one optical fiber adapted for monitoring a backscattered light from the treatment site.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the device of Sahota in view of Sinofsky and use a diffuser tip so as to provide homogenous irradiation to the treatment site. The use of a diffuse light would also reduce a damage and/or heating of the tissue that may be caused by a focused light. It would have been further obvious to one skilled in the art to use a detection system in order to monitor the treatment.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

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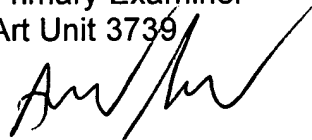
US Patent No. 5,649,923 to Gregory et al; US Patent No. 4,685,458 to Leckrone;
US Patent No. 5,466,234 to Loeb et al; and US Patent No. 5,584,872.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah
Primary Examiner
Art Unit 3739



October 1, 2005.